

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
MIDLAND/ODESSA DIVISION

STATE OF TEXAS, AND MAYO
PHARMACY, INC., A NORTH DAKOTA
CORPORATION,
Plaintiffs,

v.

XAVIER BECERRA, in his official capacity
as Secretary of Health and Human Services;
UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES;
UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES
OFFICE FOR CIVIL RIGHTS,
Defendants.

No. 7:23-cv-00022-DC

EXHIBIT 2



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES **Office for Civil Rights**

Guidance to Nation's Retail Pharmacies: Obligations under Federal Civil Rights Laws to Ensure Access to Comprehensive Reproductive Health Care Services

Pharmacies—and the pharmacists they employ—play a critical role in the American health care system. This has never been more apparent than the efforts taken to administer vaccines during the COVID-19 pandemic, for which your continued partnership has been crucial.¹ As our nation faces another significant health care crisis, this guidance is to remind the roughly 60,000 retail pharmacies in the United States² of the unique role pharmacies play in ensuring access to comprehensive reproductive health care services. This guidance covers the nondiscrimination obligations of pharmacies under federal civil rights laws.

Under Section 1557 of the Affordable Care Act (Section 1557), 42 U.S.C. § 18116, and its implementing regulation, 45 C.F.R. part 92, recipients of federal financial assistance are prohibited from excluding an individual from participation in, denying them the benefits of, or otherwise subjecting them to discrimination on the basis of sex and disability, among other bases, in their health programs and activities.³ Under Section 504 of the Rehabilitation Act of 1973 (Section 504), 29 U.S.C. 794, recipients of federal financial assistance are prohibited from discriminating in all programs and activities, on the basis of disability. Pharmacies, therefore, may not discriminate against pharmacy customers on the bases prohibited by Section 1557 and Section 504—including with regard to supplying medications; making determinations regarding the suitability of a prescribed medication for a patient; or advising patients about medications and how to take them.

The United States has the highest maternal mortality rate among developed nations; though most maternal deaths in the United States are preventable, they have been rising over the last two decades.⁴ Maternal deaths are especially high among Black women and Native American

¹ See, e.g., *The Federal Retail Pharmacy Program for COVID-19 Vaccination*, U.S. Dep't of Health & Human Servs., Ctrs. for Disease Control & Prevention (last updated June 24, 2022), <https://www.cdc.gov/vaccines/covid-19/retail-pharmacy-program/index.html>.

² IQVIA, *U.S. National Pharmacy Market Summary 2021: Market Insights Report* (2021), https://www.onekeydata.com/downloads/reports/2021_US_Pharmacy_Market_Report.pdf.

³ Covered entities should also note that Title IX of the Education Amendments of 1972 (Title IX), 20 U.S.C. § 1681 *et seq.*, prohibits discrimination on the basis of sex in education programs and activities of recipients of federal financial assistance. Pharmacies that are affiliated with a covered education program or activity are also subject to Title IX nondiscrimination requirements. See also 45 C.F.R. part 86 (HHS Title IX implementing regulations).

⁴ Roosa Tikkanen et al., *Issue Brief: Maternal Mortality and Maternity Care in the United States Compared to 10 Other Developed Countries*, Commonwealth Fund (Nov. 18, 2020),

DELIBERATIVE – PREDECISIONAL – CONFIDENTIAL DRAFT

women—regardless of their income or education levels.⁵ The Supreme Court’s decision in *Dobbs v. Jackson Women’s Health Organization*, No. 19-1392, 2022 WL 2276808 (U.S. June 24, 2022), will exacerbate these inequities and disparities for women across the country. Further, the early loss of pregnancy (before 13 completed weeks) is extremely common, experienced by about 10 percent of those who know they are pregnant.⁶ The Department is committed to improving maternal health—including for individuals who experience miscarriages—and vigorous enforcement of our civil rights laws is one way in which we plan to do so.

Pharmacies are often the most accessible health care provider for millions of Americans, with most Americans living within five miles of a pharmacy.⁷ It is estimated that more than 131 million people (66 percent of adults) in the United States use prescription medication,⁸ and therefore come into contact with pharmacies. Of the 7.6 billion retail prescription drugs filled by pharmacies in 2019, 44 percent were paid for either by Medicare or Medicaid health coverage.⁹ As recipients of federal financial assistance, including Medicare and Medicaid payments, pharmacies are prohibited from discriminating on the basis of race, color, national origin, sex, age, and disability in their programs and activities under a range of federal civil rights laws.

Among its civil rights enforcement responsibilities, the Department of Health and Human Services’ (HHS or Department) Office for Civil Rights (OCR) is responsible for protecting the rights of women and pregnant people in their ability to access care that is free from discrimination. This includes their ability to access reproductive health care, including prescription medication from their pharmacy, free from discrimination. A recent study by the Centers for Disease Control and Prevention showed that nearly 25 percent of women aged 15–49 in the United States who use contraception use some form of prescribed method (e.g., oral contraception pill, contraceptive ring).¹⁰

Furthermore, discrimination against pregnant people on the basis of their pregnancy or related conditions (examples below) is a form of sex discrimination. Such discrimination can have significant health consequences from denial of medication or treatment which can have negative health impacts on a patient. Under federal civil rights law, pregnancy discrimination

<https://www.commonwealthfund.org/publications/issue-briefs/2020/nov/maternal-mortality-maternity-care-us-compared-10-countries>.

⁵ Emily Petersen et al., *Racial/Ethnic Disparities in Pregnancy-Related Deaths — United States, 2007–2016*, 68 *Morbidity & Mortality Wkly. Rep.* 762 (2019), <https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6835a3-H.pdf>.

⁶ *FAQs: Early Pregnancy Loss*, Am. Coll. of Obstetricians & Gynecologists (last updated Jan. 2022), <https://www.acog.org/womens-health/faqs/early-pregnancy-loss>.

⁷ *Federal Retail Pharmacy Program*, U.S. Dep’t of Health & Human Servs., Ctrs. for Disease Control & Prevention (last updated June 24, 2022), <https://www.cdc.gov/vaccines/covid-19/retail-pharmacy-program/index.html>.

⁸ *Prescription Drugs*, Georgetown Univ., Health Pol’y Inst., <https://hpi.georgetown.edu/rxdrugs> (last visited June 29, 2022).

⁹ *Number of Retail Prescription Drugs Filled at Pharmacies by Payer*, Kaiser Fam. Found., <https://www.kff.org/health-costs/state-indicator/total-retail-rx-drugs/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D> (last visited June 29, 2022).

¹⁰ Kimberly Daniels & Joyce C. Abma, U.S. Dep’t of Health & Human Servs., Ctrs. for Disease Control & Prevention, Nat’l Ctr. for Health Stats., *Data Brief: Current Contraceptive Status Among Women Aged 15-49: United States, 2015-2017* (2018), <https://www.cdc.gov/nchs/data/databriefs/db327-h.pdf>.

DELIBERATIVE – PREDECISIONAL – CONFIDENTIAL DRAFT

includes discrimination based on current pregnancy, past pregnancy, potential or intended pregnancy, and medical conditions related to pregnancy or childbirth.¹¹

Examples:

- An individual experiences an early pregnancy loss (first-trimester miscarriage) and their health care provider prescribes pretreatment with mifepristone followed by treatment with misoprostol to assist with the passing of the miscarriage.¹² If a pharmacy refuses to fill the individual's prescription—including medications needed to manage a miscarriage or complications from pregnancy loss, because these medications can also be used to terminate a pregnancy—the pharmacy may be discriminating on the basis of sex.
- An individual experiences severe and chronic stomach ulcers, such that their condition meets the definition of a disability under civil rights laws. Their gastroenterologist prescribes misoprostol to decrease risk of serious complications associated with ulcers. If the pharmacy refuses to fill the individual's prescription or does not stock misoprostol because of its alternate uses, it may be discriminating on the basis of disability.
- An individual presents to a hospital emergency department with chills, fever, and vaginal bleeding. The treating physician diagnoses a miscarriage complicated by a uterine infection (known medically as a septic abortion) and orders an antibiotic. If the hospital pharmacy refuses to provide the antibiotic required for treatment because of concern that subsequent care may include uterine evacuation (via medical or surgical abortion), the pharmacy may be discriminating on the basis of sex.
- An individual who has been undergoing fertility treatments receives a positive pregnancy test. After the individual expresses concern with symptoms associated with an ectopic pregnancy,¹³ their medical provider performs an ultrasound to determine where the pregnancy is developing. The ultrasound indicates the fertilized egg is growing in a fallopian tube. The medical provider orders methotrexate to halt the pregnancy. If a pharmacy refuses to fill the prescription because it will halt the growing of cells and end the pregnancy, it may be discriminating on the basis of sex.
- An individual with rheumatoid arthritis, such that their condition meets the definition of a disability under civil rights laws, is prescribed methotrexate by their physician's assistant as a standard immunosuppressive treatment. If the pharmacy refuses to fill the individual's prescription or does not stock methotrexate because of its alternate uses, it may be discriminating on the basis of disability.

¹¹ Covered entities should also note that, while pregnancy itself is not a disability, medical issues resulting from pregnancy can qualify as a disability under Section 504 of the Rehabilitation Act of 1973 (Section 504), 29 U.S.C. § 794, which prohibits discrimination on the basis of disability in programs and activities of recipients of federal financial assistance. *Webster v. U.S. Dep't of Energy*, 267 F. Supp. 3d 246, 267 (D.D.C. 2017).

¹² Am. Coll. of Obstetricians and Gynecologists, *Practice Bulletin: Pregnancy Loss* (2018), <https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2018/11/early-pregnancy-loss>.

¹³ An ectopic pregnancy is a pregnancy that occurs when fertilized egg grows outside of the uterus. *FAQs: Ectopic Pregnancy*, Am. Coll. of Obstetricians and Gynecologists (last updated Feb. 2018), <https://www.acog.org/womens-health/faqs/ectopic-pregnancy>.

DELIBERATIVE – PREDECISIONAL – CONFIDENTIAL DRAFT

- An individual presents a prescription for an emergency contraceptive at their local pharmacy after a sexual assault to prevent pregnancy. If the pharmacy otherwise provides contraceptives (e.g., external and internal condoms) but refuses to fill the emergency contraceptive prescription because it can prevent ovulation or block fertilization, the pharmacy may be discriminating on the basis of sex.
- An individual's health care provider sends the individual's prescription for hormonal contraception (e.g., oral contraceptive pill, emergency contraception, a patch placed on the skin, a contraceptive ring, or any other FDA-approved contraceptive product) to a pharmacy. If the pharmacy otherwise provides contraceptives (e.g., external and internal condoms) but refuses to fill a certain type of contraceptive because it may prevent a pregnancy, the pharmacy may be discriminating on the basis of sex.

In addition to the aforementioned civil rights laws, OCR also enforces the Church Amendments, codified at 42 U.S.C. § 300a-7, which protect health care personnel from discrimination related to their employment because they refused to perform or assist in the performance of abortion or sterilization because of their religious beliefs or moral convictions. It also protects health care personnel from discrimination related to their employment because they performed or assisted in the performance of abortion or sterilization. This guidance does not address how the Church Amendments would apply in a given case. OCR will evaluate and apply the Church Amendments on a case-by-case basis. To learn more about OCR's enforcement of this statutory protection, see HHS's [*Guidance on Nondiscrimination Protections under the Church Amendments*](#).

For additional information, contact the Office for Civil Rights at (800) 368-1019 or OCRMail@hhs.gov. If you believe that your or another person's civil rights, conscience rights, or health information privacy rights have been violated, visit the OCR complaint portal to file a complaint online at: <https://www.hhs.gov/ocr/complaints/index.html>.

To obtain this information in an alternate format, contact the HHS Office for Civil Rights at (800) 368-1019, TDD toll-free: (800) 537-7697, or by emailing OCRMail@hhs.gov. Language assistance services for OCR matters are available and provided free of charge.

DISCLAIMER: The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or the Departments' policies.